



# California Board of Pharmacy

## State of Pedigree and EPC/RFID Standards

December 12, 2006



## Agenda

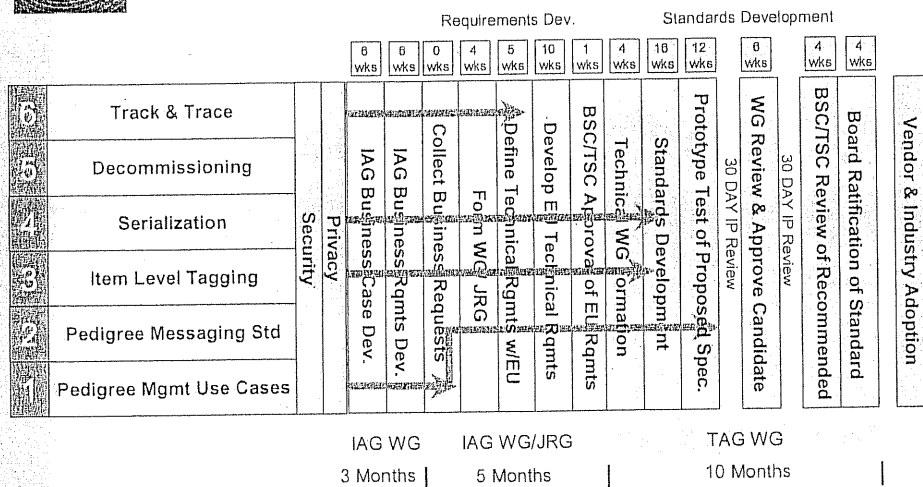
- Standards Progress
- Pedigree Review Event





# Standards Update

## Last Report

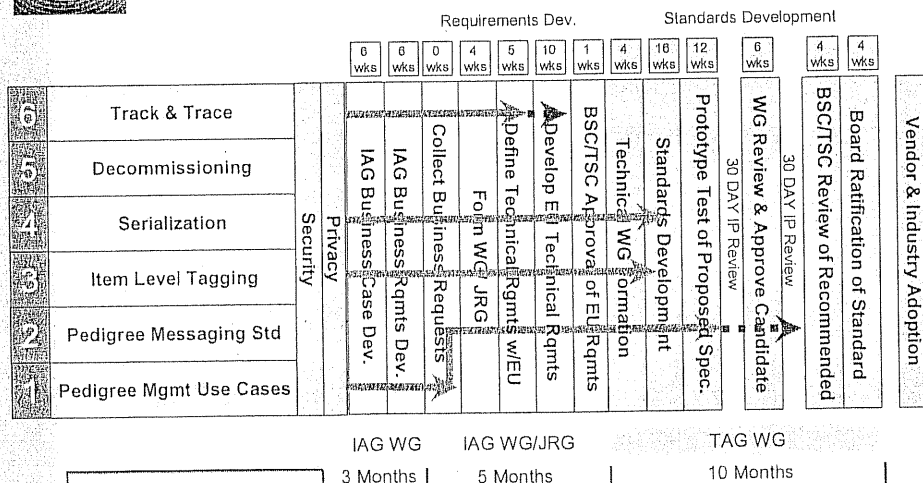


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# Standards Update

## Last Report



As of 9/26/2006  
As of 12/12/2006

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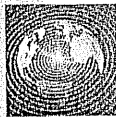
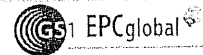
## Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define all supply chain use cases, processes and information needs for use in creating a Pedigree Messaging Standard.

**Status:** Complete

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## Standards Update

6	Track & Trace
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1	Pedigree Mgmt Use Cases

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

**Status:**

- All Standards work complete (Certification Requirements due 12/20/2006).
- Prototype event was successful.
- Passed Technical Review
- Intellectual Property Review period started

• **Ratification of standard anticipated 4Q/2006.**





## Standards Update

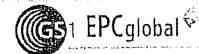
6	Track & Trace
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Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

### Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.
- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected 3Q07.

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## Standards Update

6	Track & Trace
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Define requirements the EPC identifier to be encoded on an RFID tag.

### Status:

- Requirements complete. Identified 2 GS1 Identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Joint group formed between EPCglobal Healthcare and Life Sciences Business Action Group (HLS) and GS1 Healthcare User Group (HUG).
- All remaining issues to be addressed by new Serialization group.

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## Standards Update

6	Track & Trace
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Define requirements and/or guidelines for decommissioning tags as they leave the supply chain.

### Status:

- HLS Work Group to be chartered & initiated January 2007
- Anticipate six month effort
- DEA interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry



## Standards Update

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Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

### Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges have been completed
- Common vocabularies and location identifiers have been drafted
- Additional use cases to be addressed include:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed



# Pedigree Messaging Standard

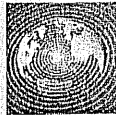
Expected Ratification by end of 2006



## Review of Pedigree Standard Features Supported

Feature	Required?	Support?
<b>Item level serialization</b> - Unique identification of each and every bottle of medication	No	Yes
<b>Electronic Signatures</b> - Ensures identity of Pedigree issuing company	Yes	Yes
<b>RFID</b> - Non Line of sight identification of Pallets, Cases or Items	No	Yes
<b>Inference</b> - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
<b>Manufacturer initiated Pedigree</b> - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes





## Next Steps

- Walk Board of Pharmacy through Pedigree scenarios
- Host workshop for Regulators from States with electronic pedigree bills
- Industry Adoption WG formed
  - Working with Industry Associations on Serialization & Item Level Tagging issues
- Upcoming events:
  - EPCglobal Inc Joint Action Group Event (Jan 8-12, 2007)
  - Ongoing work on
    - Serialization
    - Item Level Tagging
    - Track and Trace
- Provide regular status updates to CA BoP

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## Pedigree Review Event Agenda

- Structure of the Pedigree Standard
- Implementation Guidelines Review
- Walkthrough seven Pedigree scenarios
- Pedigree Software Certification Process
- Pedigree Standard Revision Process

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## Planned Activities Regional Hospital Summits

Date	City	Event
January 23 <sup>rd</sup>	Dallas	
February 20 <sup>th</sup>	California	
March 1 <sup>st</sup>	New Orleans	Healthcare Information and Management Systems Society (HIMSS)
March 13 <sup>th</sup>	Boston	
April 17 <sup>th</sup>	Chicago	
May 10 <sup>th</sup>	Washington D.C.	American Hospital Association (AHA)

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## Questions?







## Additional Slides

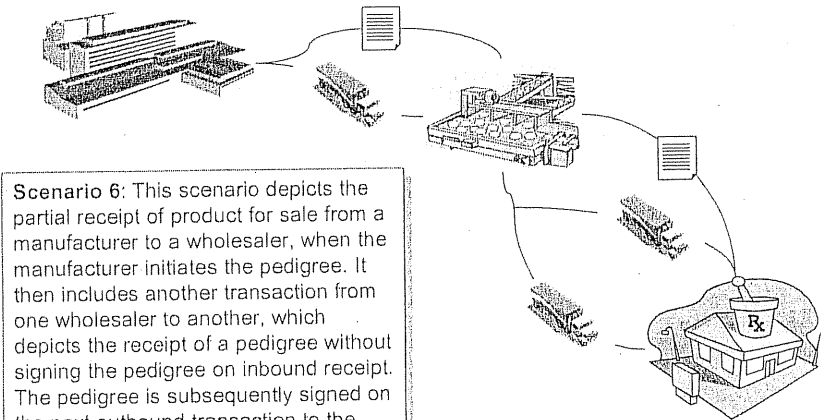


### EPCglobal Pedigree Prototype Event Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.
- **Scenario 2:** This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 3:** This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products.
- **Scenario 5:** This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.
- **Scenario 6:** This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.
- **Scenario 7:** This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.



## EPCglobal Pedigree Prototype Event Sample Scenario



**Scenario 6:** This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

